when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in § 812.3(k) of this chapter; and

(9) For near patient testing (point of care).

[65 FR 2322, Jan. 14, 2000]

## Subpart B—Diagnostic Devices

### § 892.1000 Magnetic resonance diagnostic device.

(a) *Identification.* A magnetic resonance diagnostic device is intended for general diagnostic use to present images which reflect the spatial distribution and/or magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical parameters derived from the images and/or spectra may also be produced. The device includes hydrogen-1 (proton) imaging, sodium-23 imaging, hydrogen-1 spectroscopy, phosphorus-31 spectroscopy, and chemical shift imaging (preserving simultaneous frequency and spatial information).

(b) *Classification.* Class II.

[53 FR 5078, Feb. 1, 1989]

### § 892.1100 Scintillation (gamma) camera.

(a) *Identification.* A scintillation (gamma) camera is a device intended to image the distribution of radionuclides in the body by means of a photon radiation detector. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Classification.* Class I (general controls).

[55 FR 48443, Nov. 20, 1990, as amended at 66 FR 46953, Sept. 10, 2001]

### § 892.1110 Positron camera.

(a) *Identification.* A positron camera is a device intended to image the distribution of positron-emitting radionuclides in the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Classification.* Class I (general controls).

[55 FR 48444, Nov. 20, 1990, as amended at 66 FR 46953, Sept. 10, 2001]

### § 892.1130 Nuclear whole body counter.

(a) *Identification.* A nuclear whole body counter is a device intended to measure the amount of radionuclides in the entire body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

[53 FR 1567, Jan. 20, 1988, as amended at 59 FR 63015, Dec. 7, 1994; 66 FR 38818, July 25, 2001]

[55 FR 48444, Nov. 20, 1990]

### § 892.1170 Bone densitometer.

(a) *Identification.* A bone densitometer is a device intended for medical purposes to measure bone density and mineral content by x-ray or gamma ray transmission measurements through the bone and adjacent tissues. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

### § 892.1200 Emission computed tomography system.

(a) *Identification.* An emission computed tomography system is a device intended to detect the location and distribution of gamma ray- and positron-emitting radionuclides in the body and produce cross-sectional images through computer reconstruction of the data. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Classification.* Class II.